

SUBCHAPTER K—TOBACCO PRODUCTS

PART 1107—ESTABLISHMENT REGISTRATION, PRODUCT LISTING, AND SUBSTANTIAL EQUIVALENCE REPORTS

Subpart A—Exemptions

Sec.
1107.1 Exemptions.

Subpart B [Reserved]

AUTHORITY: 21 U.S.C. 387e(j) and 387j.

SOURCE: 76 FR 38974, July 5, 2011, unless otherwise noted.

Subpart A—Exemptions

§ 1107.1 Exemptions.

(a) *General requirements.* Under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e(j)(3)), FDA may exempt from the requirements relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 910 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387j), tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if FDA determines that:

(1) Such modification would be a minor modification of a tobacco product that can be sold under the Federal Food, Drug, and Cosmetic Act (a legally marketed tobacco product);

(2) A report under section 905(j)(1) intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

(3) An exemption is otherwise appropriate.

(b) *Request for an exemption under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act.* A request for an exemption from the requirement of demonstrating substantial equivalence may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product. To request an exemption, the manufacturer must submit

the request and all information supporting the request in an electronic format that FDA can process, review, and archive. If the manufacturer is unable to submit an exemption request in an electronic format, the manufacturer may submit a written request to the Center for Tobacco Products explaining in detail why the manufacturer cannot submit the request in an electronic format and requesting an alternative format. Such request must include an explanation of why an alternative format is necessary. All submissions, including requests to submit the information in an alternative format, requests for exemptions, and all supporting information must be legible and in the English language. An exemption request must contain:

(1) The manufacturer's address and contact information;

(2) Identification of the tobacco product(s);

(3) A detailed explanation of the purpose of the modification;

(4) A detailed description of the modification, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive;

(5) A detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the Federal Food, Drug, and Cosmetic Act;

(6) A detailed explanation of why a report under section 905(j)(1) of the Federal Food, Drug, and Cosmetic Act intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health;

(7) A certification (*i.e.*, a signed statement by a responsible official of the manufacturer) summarizing the supporting evidence and providing the rationale for the official's determination that the modification does not increase the tobacco product's appeal to or use by minors, toxicity, addictiveness, or abuse liability;

(8) Other information justifying an exemption; and

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(9) An environmental assessment under part 25 of this chapter prepared in accordance with the requirements of § 25.40 of this chapter.

(c) *Exemption determination.* FDA will review the information submitted and determine whether to grant or deny an exemption request based on whether the criteria in section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act are met. FDA may request additional information if necessary to make a determination. FDA will consider the exemption request withdrawn if the information is not provided within the requested timeframe.

(d) *Rescission of an exemption.* FDA may rescind an exemption if it finds that the exemption is not appropriate for the protection of public health. In general, FDA will rescind an exemption only after notice and opportunity for a hearing under part 16 of this chapter is provided. However, FDA may rescind an exemption prior to notice and opportunity for a hearing under part 16 of this chapter if the continuance of the exemption presents a serious risk to public health. In that case, FDA will provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

Subpart B [Reserved]

PART 1140—CIGARETTES AND SMOKELESS TOBACCO

Subpart A—General Provisions

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AUTHORITY: 21 U.S.C. 301 *et seq.*, Sec. 102, Pub. L. 111-31, 123 Stat. 1776.

SOURCE: 75 FR 13230, Mar. 19, 2010, unless otherwise noted.

Subpart A—General Provisions

§ 1140.1 Scope.

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine.

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 1140.2 Purpose.

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

§ 1140.3 Definitions.

(a) *Cigarette.* (1) Means a product that:

(i) Is a tobacco product; and

(ii) Meets the definition of the term “cigarette” in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

(2) Includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.